MedLabQC

1- Statistical methods

1.1- Description of the software

MedLabQC is a programme designed for internal quality control in clinical laboratories. Two versions are available. The stand-alone version with keyboard entry of data is mainly aimed at manual analytical techniques and low throughput analysers. The automation server version, which complies with the Microsoft COM standard, can be interfaced with any laboratory information system.

The programme records the control charts, archives the data and calculates the validation ranges. Simple access to the main functions means that MedLabQC is a programme which can be immediately utilised without training by all laboratory personnel who are familiar with Levey and Jennings control charts. The number of analytes is unlimited and each is provided with up to three control levels. The three levels are validated simultaneously after display within coloured graphics (green, orange, red) which represents the control range of acceptable, warning and rejection. The Westgard's multirules $1_{3S}/2_{2S}/R_{4S}/4_{1S}/10_{m}$ are optional. Rejected control points remain displayed, however, but they are excluded from the statistical calculations. Validation of the control points can be postponed by storing data in a queue. At the end of each day, all of that day's control results can be displayed and printed. Thus daily viewing or the control performance is available in each section of the laboratory where the software is in use.

Whenever the lot number of a control material changes, the data from the previous batch are archived and the control charts of all of the relevant analytes are simultaneously restarted. All deletion and correction facilities are password-protected so they may be restricted to senior laboratory staff if desired. The data file is backed-up from time to time on a diskette at a pre-definable interval. A reminder is provided on the main screen if the backup interval has been exceeded. Exchanges between applications are possible through the clipboard or delimited text

files. A random data generator creates simulated Gaussian-distributed data and can turn the programme into an educational tool.

MedLabQC breaks new ground in data management, as explained in the following paragraphs.

1.2- Probability control limits

Traditional QC requires two nested intervals limited by warning and rejection thresholds. These limits are calculated with the formulae m±2s and m±3s where m and s are the mean and analytical standard deviation of the control material. The choice of the multiples 2 and 3 of the standard deviation dates from before the computer age when it was necessary to simplify the design of control charts as much as possible.

Unfortunately, the multiples 2 and 3 of the standard deviation do not correspond to simple probabilities. According to the Gauss distribution, an in-control analyser goes out of the interval m±2s once every 21 times and out of m±3s once every 357 times. These fractions measure the average frequency of false alarms in traditional QC. They are often unknown in spite of their major conceptual significance. A more logical approach is to define simple probability figures and abandon "rounded" limits. Moreover, it is the common rule in all biological experiments. The researcher chooses an empirical accepted risk for type I error, then deduces the decision limits.

By default the programme uses the probabilities 1/20 (5%) and 1/500 (0.2%) for false warning and false rejection. The decision limits are therefore m±1.96s and m±3.09s. The difference compared with the traditional intervals is small and normal practice remains virtually unchanged. But the probability definition of control ranges has the advantage of allowing the calculation of alarm limits with a constant risk, irrespective of the number of available control points.

1.3- Mobile limits mode

By default the programme works in a statistical mode called "mobile limits". It is also adopted when a new batch of control material is started. It allows the start of pre-control during the preliminary period. Whenever the operator validates a control point, he accepts it as consistent with the previous ones. It is then justified to include the new point in the available sample and to re-calculate a new mean and standard deviation with an additional degree of freedom. Estimations become increasingly precise. At the same time, the control limits are updated with Student's t for the two risks 1/20 and 1/500 and the new number of degrees of freedom.

Practice demonstrates that the pre-control usually becomes reliable when about 10 points have been entered. When the number reaches about 30, Student's t approximates to the standard normal variable and the limits become independent of the size of the preliminary sample (m±1.96s and m±3.09s). They are not theoretically constant, however, because m and s are always recalculated whenever a new QC point is acquired.

1.4- Locked limits mode

It may be risky to keep mobile limits too long. It is easy to imagine how a slow drift in the analyser could gradually shift the mean, widen the control ranges and prevent alarms from occurring. It is necessary to lock the computation of m and s on a reference period (the so-called preliminary period). This statistical mode is called "locked limits". With MedLabQC it is possible to select as the reference period any series of consecutive points. Each control level has its own reference period. Thus one level can be individually restarted with the analytical method staying under the control of the others.

1.5- Selecting risks

The probabilities of the controls giving a rejection signal when an analytical error is present (the probability of false rejection) and giving a rejection signal in the presence of error (the probability of error detection) are antagonistic.

When narrowing the control range, the chance of detecting an out-of-control state increases, but the number of false rejections increases at the same time. Five values are available for the probability limits of MedLabQC : 5%, 2%, 1%, 0.5% and 0.2%. By default, the risk of false alert is set at 5% and the risk of false rejection at 0.2%.

Westgard's multirules are very popular in the USA. Their efficiency is not constant. In completely random analytical series, the multirules detect more errors than the simple 1_{3s} rule but they increase at the same time the frequency of false rejections. They are mathematically equivalent to narrowing the m±3s rejection limits on a traditional QC chart. In return, with real analytical series, multirules are claimed to provide better detection of out-of-control states without increasing false rejections. This paradox is explained by the incompletely random dysfunctions of manual or automatic analytical methods. The series of control points are structured according to failure models (shift, drift ...) that are detected by Westgard's multirules with a particular efficiency. The value of multirules depends on the analytical system. They are optional in the programme.

1.6- Fixed limits mode

Statistical quality control is self-calibrated. Only the mean and analytical standard deviation define warning and rejection limits without any reference to diagnostic or therapeutic need. MedLabQC can work in a fixed limits mode where the control limits are specified empirically and independently of the analytical CV. This mode is appropriate for several laboratory situations.

Analytes with a high within-subject variability may often tolerate a higher level of imprecision without any consequence for medical decisions. Guidelines recommend careful planning of QC procedures to minimise costs. The wasteful practice of repeating analytical runs is unnecessary for drift without clinical significance. A frequently-quoted rule is that the tolerable analytical variability should be less than half the intrinsic biological variation. CLIA 88 document minimum performance characteristics which can be the basis for fixed control limits that maximise the cost-effectiveness in routine service.

Fixed limits are also mandatory in centralised QC of several identical analysers (e.g. in point of care testing). With statistical QC, a poorly maintained instrument has a larger acceptance range than one working well. It is necessary to fix absolute limits, common for all of the instruments.

Statistical QC fails with modern analysers having infrequent calibrations. To cut costs, each calibration is only duplicated or triplicated. Under those conditions, the calibration CV is not negligible compared with the analytical CV. When the method is re-calibrated, once a week, once a month or sometimes more rarely when a new batch of reagent is started, the analytical results are slightly shifted and the control materials trigger false alarms. With a fixed limit mode it is easy to define control ranges wider than m±1.96s and m±3.09s.

1.7- The common CV method

The theoretical probability of obtaining a rejection signal in a process within-control is easy to derive from the control limits. For instance, the rule 1_{3s} gives an average false rejection rate of 0.3%. But in practice, the control ranges are calculated individually for each level from the data of the preliminary period. The mean m and standard deviation s are subject to sampling errors and therefore the two limits m ± 3s. Depending on chance during the preliminary period, the real false rejection probability may fluctuate in a given chart and widely deviate from the theoretical value of 0.3%. This is particularly puzzling in a multi-level control because it can result in large differences between the rejection rates within an analyte.

When possible, it is better to avoid constructing independently the different control charts of the same analyte. The law of the common CV, whatever the concentration may be, is rather general in clinical chemistry. If verified, it is justified to estimate a common CV across the control levels and to derive the control limits from this common CV. The method equalises the false rejection probabilities for all of the control materials assigned to the same analyte. The probabilities do not vary independently any more, but do so simultaneously on the basis of the global sampling error of all of the acquired preliminary periods. Thus the frequent ambiguous situations with error signals

concentrated on a single control level are ruled out. The common CV method is adopted by default in MedLabQC for the two statistical modes : mobile and locked limits.

In the case of a two-level control, if the mean and standard deviations of the two preliminary periods are (m_1, s_1) and (m_2, s_2), the common CV is calculated with the usual common variances formula :

$$CV = \sqrt{\frac{(n_1 - 1)\frac{s_1^2}{m_1^2} + (n_2 - 1)\frac{s_2^2}{m_2^2}}{n_1 + n_2 - 2}}$$

The formula is easy to generalise for any number of control levels. In the common CV method, the control charts are constructed with the parameters (m_1, m_1.CV) and (m_2, m_2.CV) instead of (m_1, s_1) et (m_2, s_2).

2- Software configuration

2.1- Analytes

Open the menu <Parameters | Analytes> to set the analytes (also accessible with a double-click on the list of analytes in the main window). Each one is defined by four entry-fields :

- Name : Two identical names are rejected. Not case-sensitive.
- Number of control levels : 1 to 3.
- Unit : Measurement unit, either free text or unit selected from the drop down pick-list.
- Decimals : Number of decimal places for displaying and printing the control results. The mean values are displayed with an additional decimal place.

Four types of operations are possible :

- Add a new analyte : Fill in the fields of the left panel and validate with the button <Add to list> to insert the new analyte at the bottom of the list.
- Correct an analyte : Select the analyte to correct with a click on its name in the right list. Change its definition in one or several fields of the left panel. Validate the correction with the button <Replace in list>.
- Sort the analytes : The button <Sort analytes by names> sorts the analytes into alphabetical order. It is also possible to move the analytes one by one in the list through a "drag-and-drop" or with the buttons <Top> <Up> <Down> <Bottom>.
- Delete an analyte : Select the analyte to delete with a click on its name in the right list, then press the <Delete> button or the <Del> key (password-protected).

Exit from the dialogue. The above changes can be reversed with the <Undo> button as long as they have not been accepted with <OK> :

- <OK> or <Enter> key : Accepts the new list of analytes and closes the dialogue.
- <Cancel> or <Escape> key : Closes the dialogue and re-instates the previous list of analytes

- <Undo> : Re-instates the previous list of analytes.

2.2- Control materials

MedLabQC manages a list of all of the control materials used in the laboratory. Each one is registered once and then assigned to one or several analytes. In this way, whenever a lot number is updated due to a batch change, all of the relevant charts are simultaneously re-started.

Open the menu <Parameters | Control materials> to access the dialogue "Definition of control materials". Each control analyte is defined by two entry-fields :

- Name : Two identical names are rejected. Not case-sensitive.
- Lot number : Can be left empty.

Four types of operation are possible :

- Add a new material : Fill in the fields of the left panel and validate with the button <Add to list> to insert the new material in the list (alphabetical order).
- Correct a control material : Select the material to correct with a click on its name in the right list. Change its definition in one or both fields of the left panel. Validate the correction with the button <Change only the definition of materials>. All of the analytes controlled by the corrected material are simultaneously updated. Do not confuse correction and changing batch. A correction is a simple spelling change without re-starting the control charts.
- Delete a control material : Select the material to delete with a click on its name in the right list, then press the <Delete> button or the <Del> key (password-protected). Deletion is locked as long as the material is used for an analyte.
- The button <Change and erase former data> is password-protected. It is used to re-start the control charts when batches are changed. See paragraph 6.1.

The button <Material used by> displays the list of the analytes controlled by one material.

Exit from the dialogue. The above changes can be reversed with the <Undo> button as long as they have not been accepted with <OK> :

- <OK> or <Enter> key : Accepts the new list of control materials and closes the dialogue. An additional confirmation is required if lot changes have been made.
- <Cancel> or <Escape> key : Closes the dialogue and re-instates the previous list of analytes
- <Undo> : Re-instates the previous list of control materials.

2.3- Assignment of control materials to analytes

Open the dialogue "Assignment of control materials" with the button <Assign lots>. Two ways for assigning a control material to the current analyte are proposed :

- Drag and drop : Select a control material with the mouse in the left list, then drag and drop it in the right box associated with the desired control level.
- Select a control material in the left list, then transfer it in one of the right boxes with a click on a yellow arrow.

The modified boxes are indicated by a yellow background.

Exit from the dialogue. The above changes can be reversed with the <Undo> button as long as they have not been validated :

- <Change only the assignment of control materials> : Accepts the new assignment of control materials and closes the dialogue. It is a simple change of names. Do not confuse with a full lot number change with a re-start of the control charts.
- <Change and erase former data> : To re-start the control charts (password-protected). See paragraph 6.1.
- <Cancel> or <Escape> key : Closes the dialogue and re-instates the previous assignment.
- <Undo> : Re-instates the previous assignments.

3- Routine work

3.1- Main window

The whole display of the main window relates to the current analyte, the name of which can be read at the top of the right panel "Entry of QC points" (large yellow letters on a dark blue background). To change to another analyte, click on its name in the lower right list.

The nine buttons at the bottom are associated with the usual routine functions :

- <Data table> : To display and print QC data in the form of a numerical table. Incorrectly entered data can be changed or deleted.
- <Daily QC> : To display and print all of the control analyses performed on a given date.
- <Control limits> : To display and print the statistics of the quality control (mode, limits, CV ...) and to activate/deactivate the "common CV" method.
- <Print charts> : Initiates a dialogue to define the first and last date of the period to be printed.
- <Archives> : To display and print, batch by batch, the statistics and data of the previous lots of control materials.
- <Assign lots> : To assign the control materials to the different control levels of the current analyte. By default, when a new analyte is created, the control materials are called "Noname".
- <Back up> : To back up the data file on a diskette. When the interval defined in the options of the programme has been exceeded, the green indicator of the button blinks red.
- <Queue> : The counter displays the number of QC points stored in the queue. The green indicator on the button blinks red when the queue is not empty. When the button is pressed, the data of the first point in the queue are sent to the validation dialogue. If not validated, they go back to the end of the queue.
- <Exit> : To leave MedLabQC.

The more specialised functions can be accessed through the menus of the main window. Password-protection is provided whenever a correction or deletion of data is required. When the programme is first opened, the password is disabled. See paragraph 8.2 to learn how to set it again.

3.2- Control charts

The control charts are displayed in the left panel of the main window.

- A maximum of 31 points can be displayed on the screen. When the number of points exceeds 31, a scrollbar at the bottom of the charts allows navigation from the first to the last. The dates of the extreme points are displayed with a yellow background on both sides of the scrollbar.
- The green line represents the target value; the yellow and red lines represent the warning and rejection thresholds.
- The vertical scale is calculated to just include the valid control points inside the axis range. If a red line (rejection limit) falls outside, the scale is enlarged to show it on the upper or lower border of the chart.
- The light-blue points represent the points rejected at the time of validation. They are not taken into account when calculating the vertical scale. If they fall outside the axis range, they are simply displayed on the upper or lower border of the frame, whatever the value may be.
- A small flag (C) at the top of the charts is a reminder that a comment has been added to the control points.
- The statistical data displayed on the right side of the charts are relevant to the whole series of points.

Mouse actions :

- Right click on a point : A small window is opened that displays the date, the time, the numerical data, the name of the operator and any comment associated with the clicked point. Coloured spots indicate the position of the QC data compared with the control limits when validation occurred. The current position may have changed if the control limits have been modified..
- Left click on a point : The points acquired on the same date and time are selected and turn red. If the table of numerical data is opened with the button <Data table>, the cursor will be directly positioned on the line corresponding the point that was clicked upon.
- Double click on a point : Directly opens the table of QC numerical data.

3.3- Data entry

The panel "Entry of QC points" comprises the entry fields needed for acquiring QC data :

- Date and time.
- 1 to 3 analytical results according to the number of QC levels chosen for the analyte. For missing data, leave the entry field empty.
- The operator's initials, either entered or selected from the drop down pick-list. To register the usual operators in the pick-list go to the menu <Parameters | Operators>.
- Comment (maximum of 20 characters).

To navigate in the fields use the mouse or the keyboard. The <Tab> key gives the entry focus to the next field and <shift + Tab> to the previous one. Two buttons are available :

- <Clear> : Clears all of the entry fields and sets the current date and time.
- <OK> : Opens the validation window. Refer to chapter 4.

3.4- Daily summary

The window "QC daily summary" provides an overall view of the complete series of control analytes performed on a particular day in each section of the laboratory where the software is in use. The default starting date of the calendar is the current date. It can be changed at will. In each case, a coloured spot indicates the range within which a data point was located on the control chart when it was validated :

- Red spot : Rejection zone.
- Yellow spot : Alert zone.

- Green spot : Acceptance zone.
- Red cross : Result rejected by the operator.

Buttons :

- <Print> : To print the daily summary. A good practice would be to print this document every day in order to keep a daily paper-archive for the laboratory QC.
- <Today> : To reset the calendar to the current date.
- <Close> or key <Escape> : To leave the dialogue.

3.5- Table of numerical data

The window "QC data" opened with the button <Data table> displays the QC numerical data for the current analyte and allows edition of incorrect entries. In each case, the coloured spots indicate the range within which a data point is located on the control chart.

- Red spot : Rejection zone.
- Yellow spot : Warning zone.
- Red cross : This symbol indicates rejected data. These points are not included in the statistical calculations.

Buttons :

- <Print> : To print all or part of the table. Initiates a dialogue to define the first and last date of the period to be printed.
- <Edit line> : Equivalent to a double click on a line of the table. The selected line can be taken from the table and loaded again in the panel "Entry of QC points" of the main window. The data can thus be corrected and re-validated in the same way as for a first entry (password-protected).
- <Delete all> : To erase the whole table (password-protected).
- <Delete selection> : To erase the selected lines (password-protected).
- <Undo> Reinstates the original table (password-protected).
- <OK> or key <Enter> : To update the dialogue and exit from the dialogue. An additional confirmation is required if deletions are to be made.
- <Cancel> or key <Escape> : To exit from the dialogue and cancel all of the modifications.

3.6- Printing the control charts

The dialogue opened with the button <Print charts> provides 4 options :

- Full printing of the control charts or printing limited to a narrower date interval.
- Printing limited to one or two control levels among the three.
- Printing of the statistics for the selected date interval.
- Colour or monochrome printing.

4- Validation of entered data

The window "QC validation" is opened after pressing the <OK> button of the panel "Entry of QC points".

4.1- Validity indicators

Each new control point is indicated by a small black vertical line on a three-coloured horizontal bar representing the control ranges :

- Green = acceptance range.
- Yellow = warning range.
- Red = rejection range.

Each data point can be individually rejected or retrieved. Rejected points remain displayed, however, but they are excluded from the statistical calculations of m and s.

4.2- Westgard's multirules

MedLabQC implements the standard protocol $1_{3S}/2_{2S}/R_{4S}/4_{1S}/10_{m}$. Its display needs three conditions to be simultaneously fulfilled :

- The box <Westgard's rules> is checked (bottom right of the dialog).
- The QC mode is "Locked limits" or "Mobile limits". Multirules are always inactivated in the "Fixed limits" mode.
- The number of QC points is sufficient for a standard deviation s to be calculated.

The within-material rules are represented by a row of small grey ellipses under each validity indicator. The colour turns red if a rule is violated except for the rule 1:2s which is yellow coloured because it is only a warning and not a true rejection signal. According to Westgard, the rules 1:4s and 10m are only significant if associated with a 1:2s violation. They are coloured yellow in the programme if individually violated.

Westgard's nomenclature 2s and 3s has been maintained despite the probability control limits used in the software. The figures 2 and 3 should be replaced by the Student's t for the number of degrees of freedom of s and the risks selected in the configuration of the programme. It would be better here to use the terms warning deviation and rejection deviation. The meanings of the rules are :

- 1:2s = one observation in the warning zone.
- 1:3s = one observation in the rejection zone.
- 2:2s = 2 consecutive control observations in the warning zone, on the same side of the mean.
- R:4s = 2 consecutive control observations in the warning zone, on opposite sides of the mean.
- 4:1s = 4 consecutive control observations at a distance from the mean exceeding half the warning deviation.
- 10m = 10 consecutive observations on the same side of the mean.

When more than one control material is available the rules are applied across the materials. The meanings are :

- 2:2s = 2 observations simultaneously in the warning zone, on the same side of the mean.
- R:4s = 2 observations simultaneously in the warning zone, on opposite sides of the mean.
- 4:1s (in a 2-level QC) = 2 consecutive observations in each level simultaneously on the same side of the mean and at a distance from the mean exceeding half the warning deviation.
- 3:1s (in a 3-level QC) = 1 observation in each level simultaneously on the same side of the mean and at a distance from the mean exceeding half the warning deviation.
- 10 m (in a 2-level QC) = 5 consecutive observations in each level simultaneously on the same side of the mean.

- 9m (in a 3-level QC) = 3 consecutive observations in each level simultaneously on the same side of the mean.

4.3- Delayed validation

Two exits from the validation dialogue are possible :

- <OK> button or <Enter> key : The new point is inserted in the control charts. It is red-coloured for easy idenfication.
- <Cancel> button or <Escape> key : The control point is stored in the queue (first in/first out order). The counter of the <Queue> button is incremented. Delayed validation is possible. Simply press the <Queue> button to recall the data in the validation dialogue. The queue is saved on the disk (file MedLabQC.fif) for retrieval even after the computer has been switched off..

5- Control limits

5.1- Locking the control limits

The default mode of the programme is the mobile limits mode described in paragraph 1.3. When the preliminary observation period is over, the QC mode can be switched to locked limits. In that case, new data do not change either m or s.

To define the QC reference period, activate the menu <Special functions | Lock limits>. A new panel "Locking limits" appears on the right of the main window (password-protected). To select the date limits of the reference period, click with the left button of the mouse on the dates scale displayed under the charts. Two possibilities are provided :

- <Click> on one end of the date interval and then <Shift + click> on the other end.
- <Click> on one end of the date interval and then, keeping the left button down, glide the mouse towards the other end. The charts are scrolled if the cursor goes outside of the horizontal limits of the graphics.

The selected period appears in blue inverted contrast. As soon as a date interval is defined, the grid in the right panel shows the partial statistics for the chosen period. To lock a control level on this reference period, press the relevant <Lock> button. The control charts are immediately updated. The operation can be reversed with the button< Mobile>. On the charts, the reference interval is indicated by a light blue background.

Note : It is possible to lock the three control materials on the same period, to define a particular period for each one or even to mix the different modes mobile, locked and fixed in the same analyte.

Final validation :

- <OK> or <Enter> key : Accepts the new QC modes and return to "Entry of QC points".
- <Cancel> or <Escape> key : Re-instates the previous QC modes and return to "Entry of QC points".
- <Undo> : Re-instates the previous QC modes.

5.2- Fixed control limits

The importance of fixed limits is set out in paragraph 1.5. The menu <Special functions | Fixed limits> makes a new panel "Fixing control limits" appear on the right of the main window (password-protected). Three entry fields are provided for each control level :

- Target value.
- Deviation allowed before warning.
- Deviation allowed before action.

The <Fixed> and <Mobile> buttons switch each control material from one mode to the other. The control charts are immediately updated. The final validation uses the same buttons as in the previous paragraph.

5.3- Displaying the control limits

The <Control limits> button opens a window that gives a summary of all of the statistical parameters of the control :

- Names and lot numbers of the control materials.
- QC mode : mobile, locked or fixed.
- Target values, warning and rejection limits.
- Date limits for the reference period and number of QC points.
- Reference CV with which the limits are calculated and its number of degrees of freedom.. It may be either the common CV for all of the levels or the individual CV for each control material.

The checkbox <Common CV> activates the common CV method described in paragraph 1.7. When changed, the underlying charts are immediately updated.

6- Changing control materials and archiving

Three changes are needed whenever a new control material is introduced :

- Updating of the name and lot number.
- Re-starting the analytes controlled by the material. The data relating to the older batch are erased and the charts are cleared.
- Archiving the data for each analyte in a special file. An <Archive> button is provided for consulting old batches.

Three ways of archiving are provided by MedLabQC.

6.1- Simultaneously re-start all of the analytes

This is the most frequently used procedure. A batch of control material is exhausted and replaced by a new one. All of the analytes controlled by the former batch have to be simultaneously initialised.

Open the window "Definition of control materials" with the menu <Parameters | Control materials>. Change the lot number and the name if necessary. Validate with the button <Change and erase former data> (password-protected). The new lot appears in the right list with a red cross as a reminder for data deletion. It is possible to re-start simultaneously several control materials. All of the changes can be reversed as long as neither the <OK> button or the <Enter> key have been pressed. A final security confirmation is required before each deletion of data.

6.2- Re-start analyte by analyte

Sometimes it is useful to change a control material for only one analyte, keeping the former material for the remaining analytes. First, register the name and the lot number of the new material in the window "Definition of control materials" (menu <Parameters | Control materials>). Next select the analyte to be updated in the main window and press the button <Assign lots> to open the dialogue "Assignment of control materials".

Make the changes as indicated in paragraph 2.3 and validate with the button <Change and erase former data> (password-protected). A security confirmation is required before the deletion of data.

6.3- Initialisation of one control chart

It is possible to erase all of the data in one chart without changing the control material. The menu <Special functions | Erase/archive levels> opens a panel "Erasing QC levels" on the right of the main window. Clear the control charts with the buttons <Erase/archive data>. The points appear grey. They can be retrieved with the button< Un-erase data>.

Final validation :

- <OK> button or <Enter> key : Accept the modifications and return to "Entry of QC points".
- <Cancel> button or <Escape> key : Cancel the modifications and return to "Entry of QC points".

7- Files and exchanges between applications

MedLabQC stores data in a file "MedLabQC.qcf" (qcf for Quality Control File). Backward compatibility with the previous programme QualCont is ensured. Exchanges with other applications are made possible through the clipboard or delimited text files.

7.1- Retrieving the data file of QualCont

MedLabQC can read the data file of QualCont 2. Data can be retrieved either from the backup diskette or from the disk. Click on the menu <File | Import> to open the file selection dialogue. Drop down the picklist "type". Three types of file are available :

- Text file from spreadsheet (*.txt) : See paragraph 7.2.
- Data file of QualCont 2 (*.dat) : To load the file from the hard disk.
- Backup file of QualCont 2 (*.sav) : To load a backup file from a diskette.

Select (*.dat) or (*.sav) and find the QualCont file in the tree of the sub-directory/reader where it is stored. The analytes of the former programme are loaded with all of the control points. Only the names of the control materials are lost. It is necessary to enter them again manually (menu< Parameters | Control materials>) and assign them to the relevant analytes (button <Assign lots>).

7.2- Exchanges between applications through text files

MedLabQC can export the data of each analyte to a text file with fields delimited by tabulations. The data are organised in 5 to 7 columns : date, time, control levels (1 to 3), operators' initials and comments. This kind of file can be read by any word processor or spreadsheet programme. Click on the menu <File | Export> to type in the name of the export file.

MedLabQC can import a text file delimited by tabulations. The first column must contain valid dates. The second column is reserved for times. If it is empty or if the format is not valid, the default time 12:00:00 is used. The next three columns are reserved for the results of the three control levels. Any additional columns are ignored. Imported data are inserted in the current analyte. To prevent any mixing of data, it is advised that the current analyte is cleared or a new one created before importing.

7.3- Exchanges between applications through the clipboard

A simple exchange method is copy/paste. Use the menus <Clipboard | Copy> and <Clipboard | Paste>. The rules are the same as in paragraph 7.2.

7.4- Archive files

Control points erased in a chart following the change of a control material are stored in archive files named QCXXXXXX.qca (qca for Quality Control Archive) where "XXXXXX" is a number incremented from 000001 to 999999. They are also text files with fields delimited by tabulations, which are easy to read with any word processor or spreadsheet programme.

8- Miscellaneous functions

8.1- Backup

It is advised that a data backup is performed regularly on a diskette. MedLabQC provides a reminder for the operation. Open the dialogue "Backup/restore options"with the menu <Configuration | Backup/restore options> . Enter a backup interval in days (default 7 days) and select the drive letter (usually A or B) where the following files will be copied : MedLabQC.sav (last backup) and MedLabQC.old (previous backup).

When the backup interval has elapsed, the green spot in the button <Backup> of the main window blinks red. To back up, simply click on this button after placing a diskette in the drive. To restore click on the menu< File | Diskette restore>.

8.2- Password-protection

Correction/deletion operations are not normally available to some grades of laboratory staff, but are restricted to senior staff. These operations are password-protected. When the programme is initially opened, the password-protection is inactivated. To re-activate it, open the dialogue "Change password" with the menu< Configuration | Password>. Fill in the fields "New password" and "Confirm password" and validate with< OK>. If the two entry fields are left empty, the password-protection disappears again.

8.3- Random data generator

The random data generator is started with the menu <Special functions | Random generator>. It creates simulated Gaussian-distributed data to provide the user with an easy means of learning how to use the software and to test it. The new data can be either stored in the queue or directly inserted in the charts. The entry fields are :

- Random data in queue : The new points are stored in the queue to be recalled and validated later one by one with the button <Queue>.
- Random data in charts : The new points are directly inserted in the charts.
- Number of points : Number of points to create.
- First date : One point will be created every day from that first date.
- QC Time : Time for all of the created points.
- m and CV : Distribution parameters for the simulated points. The CV is expressed in %. To leave a control level empty, leave empty the fields "mean" and/or "CV" in the entry table.